Section 5: 510(k) Summary

JUN 0 7 2013

The following information is provided as required by 21 CFR § 807.87 for the iSR'obot Mona Lisa 510(k) premarket notification.

Sponsor: BioBot Surgical Pte Ltd.
2 Woodlands Spectrum #03-10
Woodlands Sector1, Singapore 738068
Establishment Registration: Pending

Contact: Quality Systems and Solutions Pte Ltd
20 Maxwell Road, #09-17,Maxwell House
Singapore 069113

Phone: +65 31507191
Fax: +65 6507 0368 (Attn: Biobot Surgical Pte Ltd)
Email: john@quasys.net

Date of Submission: April 2, 2013
Proprietary Name: iSR'obot Mona Lisa
Common Name: system, image processing, radiological
Regulatory Class: II
Regulation(s): 892.1560 Ultrasonic pulsed echo imaging system
892.1570 Diagnostic ultrasonic transducer
Product Codes: IYO, ITX
Panel: Radiology
Predicate Device: iSR'obot Mona Lisa (K111347)

Device Description: iSR'obot Mona Lisa is a platform-hosted motorized device integrating a probe-driving system for 3-D image collection and a precise biopsy guidance mechanism (biopsy needle platform) to control the orientation of needle insertion and depth of puncture to assist the surgeon perform targeted transperineal prostate biopsy in conjunction with the guidance of transrectal ultrasound. The device serves as a needle guide only.

The device has a graphics user interface (GUI) that can provide a complete view of the 3D prostate to the physicians by hands-free image acquisition. The prostate segmentation tool allows a manual or automatic surface detection from the 3D image, based on which the prostate volume is calculated and the systematic biopsy plan is generated. This plan can be customized and the approved plan will be used to control the biopsy needle platform to guide the needle positioning for the manual puncture.

Indications for Use: iSR'obot Mona Lisa is intended for use by a trained urologist or physician to perform the computer-assisted transperineal prostate biopsy under transrectal ultrasound guidance. The device serves as a biopsy needle guide only. It shall be used in conjunction with a third party ultrasound machine and endorectal probe that supports BMode, and a third party prostate biopsy gun and needle. The insertion of biopsy needle will be done by urologist.

Intended Use: iSR'obot Mona Lisa serves as a biopsy needle guide to assist the surgeon in performing targeted transperineal prostate biopsy in adult males in conjunction with the guidance of transrectal ultrasound.

Technological Characteristics compared to those of predicate device: Like iSR'obot Mona Lisa (K111347), the modified device utilizes similar technology to acquire transrectal ultrasound image to plan and guide a prostate biopsy procedure. Both devices are platform hosted motorized device and are able to provide transverse view, sagittal view and 3D view of prostate gland. Regarding to the needle guiding mechanism, both iSR'obot Mona Lisa and modified device can identify the direction and depth for biopsy needle. Thus the fundamental scientific technology of both iSR'obot Mona Lisa (K111347) and the modified device are the **same**.

Non-clinical Testing: Bench and simulated use testing, including phantom testing, confirm that the subject device performs as intended and is substantially equivalent to the predicate devices.

Clinical Performance: No clinical data is submitted in support of this submission.

Substantial Equivalence/Conclusions: The claim of substantial equivalence of iSR'obot Mona Lisa to the products identified above is based on the comparison of the regulatory characteristics, product technical characteristics, and performance.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 7, 2013

Biobot Surgical Pte Ltd.
% Mr. John Baby
Chief Consultant
Quality Systems and Solutions Pte Ltd.
20 Maxwell Road, #09-17, Maxwell House
SINGAPORE 069113

Re: K130944
Trade/Device Name: iSR'obot Mona Lisa
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, ITX
Dated: May 22, 2013
Received: May 31, 2013

Dear Mr. Baby:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Janine M. Morris
Director, Division of Radiological Health
Office of In-Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130944

Device Name: iSR'obot Mona Lisa

Indications for Use:

iSR'obot Mona Lisa is intended for use by a trained urologist or physician to perform the computer-assisted transperineal prostate biopsy under transrectal ultrasound guidance. The device serves as a biopsy needle guide only. It shall be used in conjunction with a third party ultrasound machine and endorectal probe that supports BMode, and a third party prostate biopsy gun and needle. The insertion of biopsy needle will be done by urologist.

Prescription Use _X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

(Division Sign Off)

Division of Radiological Health

Office of *In Vitro* Diagnostics and Radiological Health

510(k) K130944